

RESEARCH ARTICLE

A comparison of MRI and intraoperative measurements to determine interspinous spacer device size

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Abstract

Purpose: To determine whether preoperative magnetic resonance imaging (MRI) can reliably determine intraoperative measurements in the Vertiflex Interspinous Spacer (ISS) procedure.

Methods: Patients who underwent Vertiflex ISS with Lumbar Spinal Stenosis (LSS) and a preoperative MRI available in picture archiving and communication system (PACS) between January 2013 to February 2023 were identified retrospectively from the University of Chicago Medical Center Database. An experienced board-certified pain specialist and well-trained 2nd-year medical student independently performed measurements of the interspinous space where Vertiflex ISSs of various sizes are inserted. MRI measurements were taken blinded to intraoperative measurement and ISS implant size used in the procedure. Pearson's correlation, paired T-test, intraclass correlation coefficients (ICC), absolute agreement, and 2-way random effects model were used to determine the relationships between MRI, intraoperative measurement, and ISS size.

Results: A total of 79 patients who underwent the Vertiflex ISS procedure were included in the study. Median Vertiflex ISS size was 10 mm (10–12), mean intraoperative measurement was 11.40 mm (± 1.23), and mean MRI measurement was 11.24 mm (± 1.44). Mean differences were not significant in intraoperative and MRI measurements ($p = 0.271$). Pearson's correlation between ISS size and intraoperative measurement was 0.807 ($p < 0.001$), representing the current best practice model. Pearson's correlation was 0.668 ($p < 0.001$) between MRI measurement and ISS size and 0.542 ($p < 0.001$) between MRI and intraoperative measurement. ICC showed good agreement and moderate reliability (0.698) between intraoperative and MRI measurements. Observer interrater ICC agreement of the MRI interspinous space measurement was 0.95 ($p < 0.001$).

Conclusions: Measuring interspinous space on MRI yielded, on average, a value smaller than the intraoperative measurement in Vertiflex ISS procedures, but the mean differences were not significant. Good agreement and moderate reliability were found between observer MRI and surgeon intraoperative measurements, suggesting MRI can evaluate the intraoperative space for the Vertiflex ISS procedure. Preoperative MRI measurement may help decrease complications by aiding in surgical decision-making through providing a reference for intraoperative measurements. Further prospective study is necessary to determine if preoperative MRI measurement can predict and potentially replace the need for intraoperative measurement.

KEY WORDS

anthropometric measurements, Interspinous spacer (ISS), lumbar spinal stenosis (LSS), MRI

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INTRODUCTION

Lumbar spinal stenosis (LSS) is a common cause of back and leg pain in the elderly population. It is the most common indication for spinal surgery in patients older than 65 years. The condition is characterized by pain or cramping in the legs brought on by walking and relieved by resting or leaning forward. The most common etiology is a degenerative process affecting the lumbar spine, causing hypertrophy of the ligaments, facet joints, or disc bulging, resulting in spinal canal narrowing. The diagnosis is confirmed by spine imaging. The US Social Security Act recognizes spinal stenosis as a disabling condition.¹

Failure of conservative treatment warrants consideration for surgical options, most commonly laminectomy with or without fusion.^{2,3} This procedure is associated with high cost and morbidity,⁴⁻⁷ and a meta-analysis study showed that only 64% of patients treated surgically for LSS reported good-to-excellent outcomes at an average of 4 years of follow-up.³ Worsened instability may result from decompression alone, especially in the setting of spondylolisthesis.

Alternatively, fusion has inherent risks of nerve injury, nonunion, and adjacent segment degeneration. Interspinous spacers (ISS) are a less-invasive approach to surgical decompression in patients with failed nonsurgical management. The Superior Interspinous Spacer (Vertiflex Inc., San Clemente, CA) is an FDA-approved intervention for treating symptomatic LSS.⁸ Compared to other ISS, Vertiflex was designed to be implanted between contiguous spinous processes via a less-invasive approach percutaneously as a single piece through a cannula after dilators have opened the interspinous space.^{9,10} The device consists of an implant body and two cam lobes that rotate during deployment to encompass the lateral aspects of the superior and inferior processes. Device size ranges from 8 to 16 mm, corresponding to the magnitude of desired distraction between the two spinous processes (Figure 1). Sizing is an essential aspect of the Vertiflex ISS procedure. Intraoperative anthropometric measurements must be taken to implant the device correctly using an interspinous gauge where

positioning is confirmed under fluoroscopy. Confidence in correct sizing is important, as incorrect size implant placement can lead to possible complications: (1) Oversize implant causes over-distraction of the supraspinous ligament, causing pain, and by over-distraction of the spinous processes, can result in spinous process fracture. (2) Undersized interspinous device by under stabilizing can induce segmental kyphosis, resulting in an under-distraction of the ligamentum flavum which can then buckle into the spinal canal causing persistent symptoms from LSS.^{11,12} Taking repeated intraoperative measurements to get a reliable measurement adds time to the procedure. On occasion, the selected size of the Vertiflex device still may not fit the measured interspinous space, forcing a new size to be implemented or repeat procedure. Gazzeri et al. found a complication rate of 7.8% among 1108 patients who underwent placement of an ISS—complications including spinous process fracture, dura mater tears, and cerebral spinal fluid leakage. The rate of repeat surgery was 9.6%.¹¹

The current practice relies on fluoroscopic guidance for ISS size measurement but the fluoroscopic view is not always perfect which can complicate proper size selection. There are no guidelines or recommended preoperative planning tools to consider before the procedure for optimal ISS size selection and there has been no study of the prevalence of placement discrepancy in size selection vs. interspinous space. Though MRI modalities have generally been shown to be effective in detecting and diagnosing LSS, few studies have explored the ability of MRI to characterize the space measured intraoperatively for placement of the ISS. Jang and Park did a morphometric study of lumbar interspinous space in 100 patients using MRI at Stanford Medical Center. However, patients did not have diagnosis of LSS, and the MRI measurements were not used to correlate with any intraoperative measurements. Instead, it gave a general measurement value of the interspinous space between contiguous lumbar vertebrae.¹⁴ Studies in other specialties have shown that MRI can better predict intraoperative measurements, but the concept of a preoperative MRI measurement protocol is novel, and currently no prospective publications exist on the

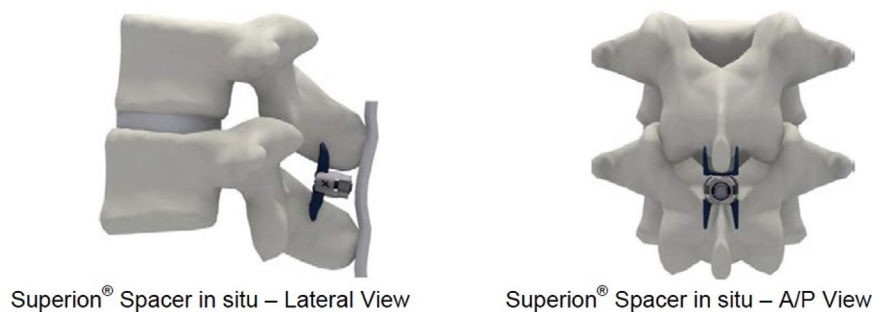


FIGURE 1 Vertiflex Interspinous Spacer Inserted in Sagittal and A/P Views. A spacer is inserted at the junction of the lamina and spinous process.¹³

topic.^{15–17} This study aimed to determine whether preoperative MRI measurements can reliably predict intraoperative space measurements in the ISS procedure. It was hypothesized that MRI space measurements at the level of the Vertiflex ISS insertion would be reliably correlative with intraoperative measurements in the Vertiflex ISS procedure. If reliably correlative, preoperative MRI measurements can assist in preoperative planning and increase physician confidence in intraoperative measurements by providing comparative insight on expected interspinous measurements. Assuring correct sizing will lead to improved outcomes, decreased complications, and hopefully, a lower need for repeat surgical evaluation.¹⁸

METHODS

This was a single-center, retrospective study performed at a tertiary care center. Before the review, the design and protocol were approved by authors' institutional review board (No. 23-0705). Consent was waived for review of medical documentation and imaging.

Patient selection

Patients who underwent Vertiflex interspinous spacer placement for LSS performed by three different pain specialists at the University of Chicago Medical Center between January 2013 and February 2023 were identified retrospectively. LSS was defined and graded using Schizas grading system.¹⁹ Inclusion criteria consisted of patients who underwent Vertiflex Interspinous Spacer placement with a diagnosis of LSS by MRI and recorded intraoperative measurement of the space at the junction of the lamina and spinous process at the vertebral level of spacer placement. The exclusion criteria included if no intraoperative measurements for the Vertiflex Interspinous Spacer were recorded. Basic demographic information (age, sex, height, and body mass index (BMI)), imaging and procedure findings were obtained from patient charts.

Imaging evaluation

MRI studies were obtained from picture archiving and communication systems (PACS), which were accessed through patient charts at the host institution. All measurements were independently performed by two observers; a board-certified anesthesiologist and pain specialist, and a postgraduate degree medical student after extensive training in taking measurements on a PACS workstation (IntelliSpace PACS Enterprise; Philips North America) using the PACS measurement tool (IntelliSpace, Philips, Netherlands). Training

consisted of specialist observation and student reproduction of measurements on 5 different cases before starting data collection. Subsequently, the physician and medical student independently reviewed and made all MRI measurements. The space at the junction of the lamina and spinous process at the vertebral level of spacer placement was the primary measurement, as this is where the Vertiflex ISS is implanted during the procedure. Secondary measurements at the level of the spacer included:

- Length of the spinous process.
- Width of the spinous process.
- Space at the base of the spinous process and space at the tip of the spinous process.

The imaging plane was centered on the spinous process using a scout line and localizer at the vertebral level of the spacer in both axial and sagittal sequences (Figure 2). All MRI measurements were made blinded to the intraoperative measurements, and intraoperative measurements were only recorded after review of the MRI. Additionally, the same approach was taken for measurements at all vertebral levels.

Statistical analysis

Quantitative data were expressed as mean with standard deviation (SD) or median with interquartile range (IQR), and categorical data were expressed as frequency and percentage. The Shapiro–Wilk test was used to evaluate the distribution of the continuous data. The anesthesiologists' measurements were used for analysis. Pearson's correlation analysis was used to assess the correlations of ISS size (Implant size), intraoperative measurement (Intraoperative), MRI measurement (MRI), days between MRI and procedure (days MRI – Proc), length of the spinous process (Length of SP), width of the spinous process (Width of SP), space at the base of the second spinous process (Space at base), and space at the tip of the spinous process (Space at tip). For Pearson's correlation coefficient interpretation, the correlation was classified from 0 to 0.10 as negligible, 0.10 to 0.39 as weak, 0.40 to 0.69 as moderate, 0.70 to 0.89 as strong, and 0.90 to 1 as very strong. The Bonferroni correction was applied to the P-values to correct for multiple comparisons. A paired t-test was performed to compare differences between the MRI and intraoperative measurements. Comparison of agreement and reliability of MRI and intraoperative measurements was quantified with intraclass correlation coefficient (ICC) using the two-way random effects models of the absolute agreement. The two editors' measurements were compared for interrater reliability using the same ICC model. The intraclass correlation coefficient (ICC) is frequently used to evaluate reliability to reflect both the degree of correlation and agreement between measurements. It is a value from 0 to

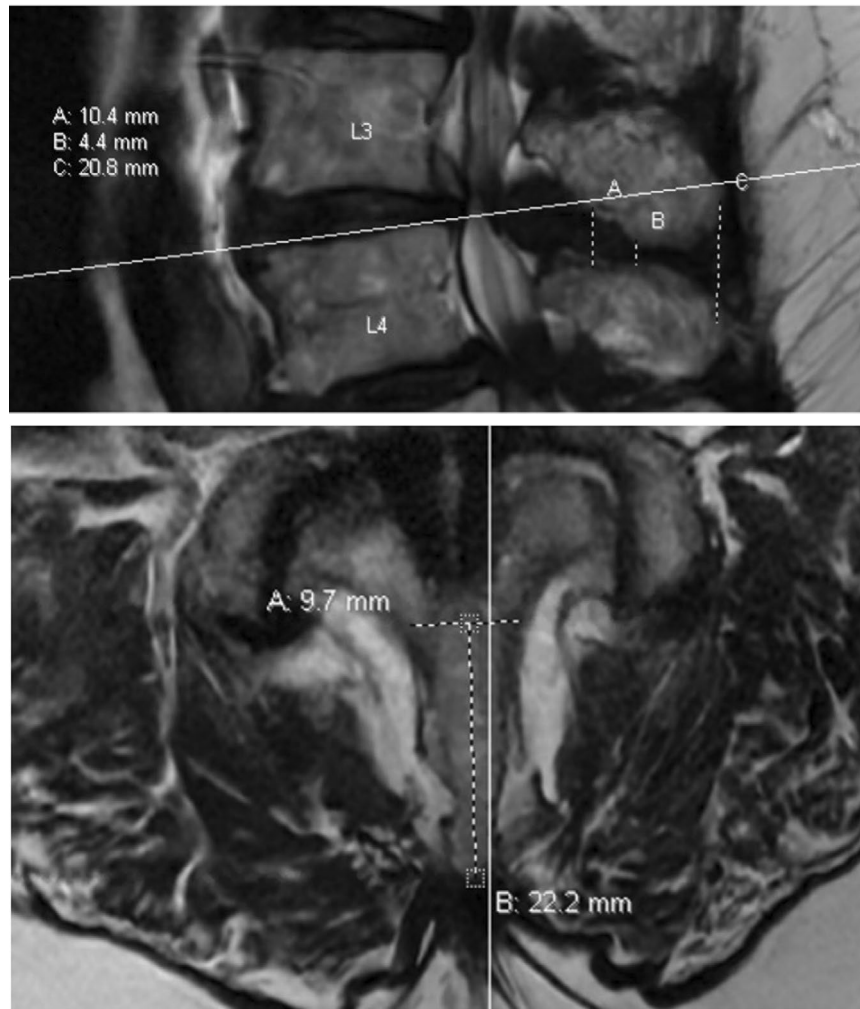


FIGURE 2 MRI measurements using PACS Workstation at the level of Vertiflex ISS Implementation on preoperative imaging. The scout line is shown in both images for alignment. (A-above) Measurement at the junction of lamina and interspinous process. (B-above) Measurement of smallest space between contiguous spinous processes. (C) Measurement of space between tips of spinous processes. (A-below) Measurement of the width of the spinous process. (B-below) Measurement of the length of the spinous process from the ISS insertion point to the tip of the spinous process.

1, where lower values indicate poor reliability and higher values indicate excellent reliability. The anesthesiologist's measurements were used for reliability between arthroscopic intraoperative measurements and MRI measurements. For ICC interpretation, the classification of agreement and reliability described by Cicchetti and Koo and Li was used, respectively.^{21,22} The Bland–Altman plot was used to analyze and illustrate the agreement between MRI and intraoperative measurements. All the statistical analyses were performed using Stata/SE (Version 18, Stata Corp, USA). A p -value <0.05 was used to consider statistical significance.

RESULTS

The study initially included 84 patients; however, 3 patients did not have MRIs available in the system, 1 patient

had an MRI done at an outside hospital and did not have enough slices to do measurements at the vertebral level of the procedure, and 1 patient did not complete the procedure due to intraoperative complications unrelated to the ISS implant. These 5 patients were excluded from the study, leaving a total of 79 patients for analysis. Of these 79 cases, the mean age was 76.51 (± 8.05), 43 were female, and the median BMI of all cases was 28.8 (kg/m^2 , 25.8–34.2) (\pm SD, [Table 1](#)). The most common level of LSS was L4–L5, with 25 cases of grade 1 spondylolisthesis at the vertebral level of the implant and 11 instances of trace spondylolisthesis at this level. Seventeen patients had a two-level implant. There were 5 total complications associated with the procedure. There were 3 changes in the size of the ISS due to it not fitting the anatomical space, 1 aborted procedure, and there was 1 case where the spinous segment was fractured intraoperatively. MRI and procedural data can be seen in [Table 1](#).

TABLE 1 Patient demographic, MRI, and procedure characteristics.

Variables	Overall (N=79)
Demographics	
Age, mean (SD)	76.51 (8.05)
Sex at birth, <i>n</i> (%)	
Male	36 (41.8)
Female	43 (58.2)
BMI (kg/m ²), median (IQR)	28.8 (25.8–34.2)
MRI Measurements	
Preoperative implant size (mm), median (SD)	10 (10–12)
MRI measurements (mm), mean (SD)	11.68 (1.70)
Level of vertebrae the vertiflex interspinous spacer ^a , <i>n</i> (%)	
L1–L2	3 (3.8)
L2–L3	5 (6.3)
L3–L4	30 (38.0)
L4–L5	41 (51.9)
Length of spinous process (mm), mean (SD)	25.19 (3.83)
Width of spinous process (mm), median (IQR)	9.1 (7.8–10.9)
Days between MRI and procedure, median (IQR)	205 (78–377)
Space at the base of the spinous process (mm), median (IQR)	5.1 (4.1–6.6)
Space at tip of spinous process (mm), mean (SD)	14.84 (6.44)
Second interspinous spacer placed ^a , <i>n</i> (%)	16 (20.25)
Measurement between the junction, mean (SD)	11.05 (1.94)
Level of vertebrae, <i>n</i> (%)	
L2–L3	1 (6.25)
L3–L4	5 (31.25)
L4–L5	9 (56.25)
L5–S1	1 (6.25)
Length of spinous process (mm), median (IQR)	25.3 (21.65–28.2)
Height of the spinous process (mm), median (IQR)	9.7 (8–10.95)
Space at the base of the second spinous process (mm), mean (SD)	4.71 (2.13)
Space at the tip of the spinous process (mm), mean (SD)	15.35 (6.55)
Procedure Characteristics	
Complication associated with the implant procedure, <i>n</i> (%)	5 (6.33)
Aborted procedure ^a , <i>n</i> (%)	1 (25)
Change in the size of the vertiflex interspinous spacer, <i>n</i> (%)	3 (60)
Vertiflex interspinous spacer size changed to (mm), median (IQR)	10 (8–10)
Break of the vertiflex interspinous spacer, <i>n</i> (%)	0 (0)
Fracture of the spinal segment, <i>n</i> (%)	1 (20.0)
Flouro Time (seconds), median (IQR)	202.6 (149.4–256.7)
Intraoperative measurement, mean (SD)	11.41 (1.24)
Post-operative size of implant (mm), median (SD)	10 (10–12)
Grade of spondylolisthesis at the level of implant, <i>n</i> (%)	
Grade I	18 (22.78)
Trace	9 (11.39)
None	52 (65.82)
The same procedure, <i>n</i> (%)	16 (20.25)
Postoperative size of the second implant (mm), mean (SD)	11 (1.03)
Measurement of space at the junction (mm), median (IQR)	12 (10–12)
Grade of spondylolisthesis at the level of the implant, <i>n</i> (%)	
Grade I	5 (31.25)
Trace	2 (12.5)
None	9 (56.25)

Note: MRI measurements pertain to values recorded by the pain specialist. Procedure measurements are statistically representative of measurements taken by all three pain specialists.

^aValid percentage due to missing values.

The median Vertiflex ISS size was 10 mm,^{10–12} the mean intraoperative measurement was 11.40 mm (± 1.23), and the mean MRI measurement was 11.23 mm (± 1.44), as seen in Table 2. The mean differences between intraoperative and MRI measurements were insignificant ($p=0.271$). Average measurements at ISS sizes 8, 10, 12, and 14 mm were 8 mm, 10.73 mm (± 0.92), 12.1 mm (± 0.31), and 14 mm intraoperatively, and 8.8 mm, 10.55 mm (± 1.03), 11.96 mm (± 1.23), and 13.68 (± 0.13) for MRI, respectively (Table 2). Comparisons for ISS sizes 8 and 14 mm were negligible due to the small sample size. Pearson's correlation between ISS size and intraoperative measurement was strong (0.807, $p<0.001$), representing the current best practice model. Pearson's correlation between MRI measurement and ISS size was moderate (0.668, $p<0.001$) and moderate (0.542, $p<0.001$) between MRI and intraoperative measurement. All other correlations between variables were weak or negligible (Figure 3).

Additionally, ICC showed good agreement and moderate reliability (0.698) between intraoperative and MRI measurements. Interrater MRI was excellent at all measurements. ICC for measurement at junction of lamina and interspinous process, smallest space between contiguous spinous process, width of spinous processes, space

between tip of spinous processes, and length of spinous process was 0.95, 0.88, 0.96, 0.96, and 0.98, respectively (Table 3). p values for ICC values were significant for all intraoperative vs. MRI measurements, as well as for interrater MRI assessments.

Bland Altman plot was drawn to visually compare the magnitude of differences between measurements (Figure 4). A level of agreement within 2 mm of the mean difference was distributed similarly between intraoperative and MRI measurements. The 2 mm range is clinically significant as ISS sizes vary by 2 mm, and during placement can always be sized down from the intraoperative measurement. Differences greater than 2 mm from the mean difference between intraoperative and MRI measurements had the most significant variability.

DISCUSSION

The most important finding of this study was that the average interspinous space measurement on MRI was not significantly different from the average intraoperative measurement ($p=0.271$). Further, the Bland–Altman

TABLE 2 Comparison of MRI vs. intraoperative measurement by implant size.

Sample size (<i>N</i>)	MRI measurement in mm (SD)	Intra-operative measurement in mm (SD)	Implant size used in mm
1	8.6	8	8
44	10.55 (1.03)	10.73 (0.92)	10
29	11.96 (1.23)	12.10 (0.31)	12
5	13.68 (0.13)	14 (0)	14

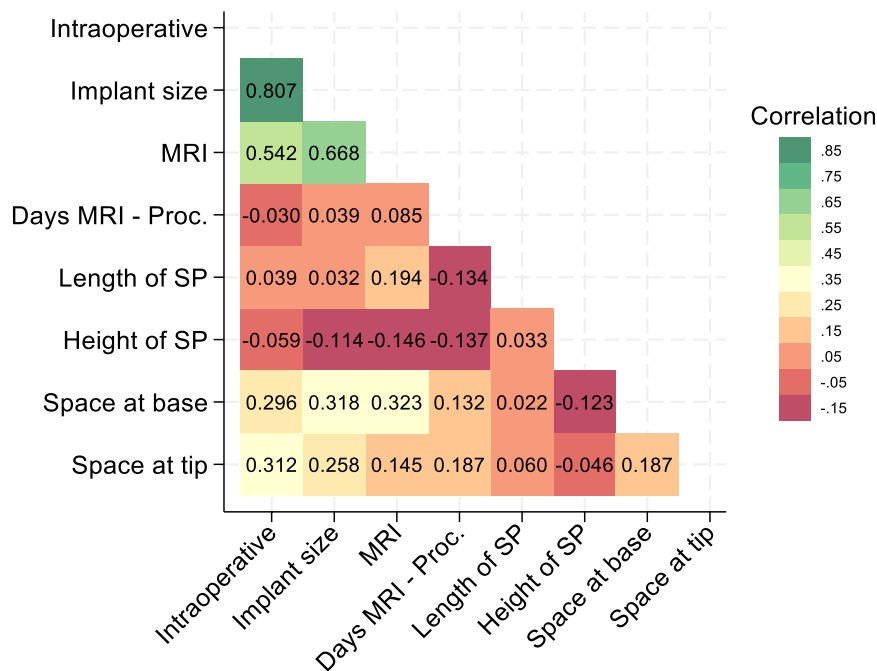


FIGURE 3 Pearson's correlation between variables of clinical significance.

TABLE 3 Comparisons and Intraclass correlations coefficients (ICC).

Pair	Measurements (mm) mean (SD)	<i>p</i> -value	ICC	95% CI
Intraoperative vs. MRI	11.41 (1.24) vs. 11.23 (1.44)	0.271	0.698	(0.53–0.81)
Observer 1 vs. 2				
Junction of Lamina and Interspinous Process	11.23 (1.44) vs. 11.68 (1.71)	–	0.946	(0.79–0.98)
Smallest Space Between Contiguous Spinous Processes	5.54 (2.03) vs. 5.24 (2.47)	–	0.876	(0.81–0.92)
Width of Spinous Process	9.47 (2.44) vs. 9.69 (2.70)	–	0.956	(0.93–0.97)
Space Between the Tip of the Spinous Processes	14.93 (5.79) vs. 14.87 (6.47)	–	0.958	(0.93–0.97)
Length of Spinous Process	25.29 (3.61) vs. 25.2 (3.85)	–	0.979	(0.96–0.99)

Abbreviation: CI, Confidence interval.

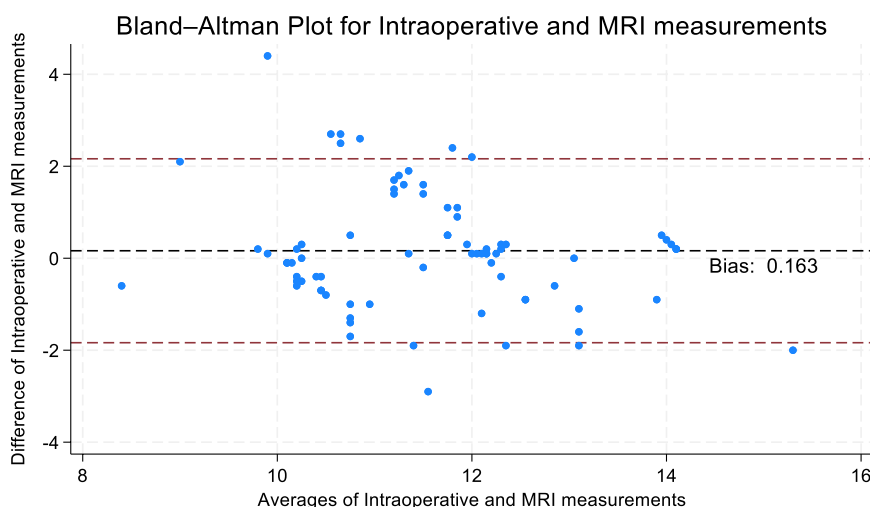


FIGURE 4 Bland–Altman plot of Intraoperative and MRI measurement, depicting the level of agreement between modalities. Differences in MRI measurement values minus intraoperative values were plotted against mean measurements. The mean difference (dotted black line) and range of 2 mm from the mean difference (orange dotted lines) are marked to show how many measurements were within 2 mm of the mean difference. As aforementioned, being within 2 mm is clinically a significant cutoff value as ISS sizes vary by 2 mm. Hence 2 mm was assigned as the cutoff threshold. Thus a level of agreement between Intraoperative and MRI measurements outside of 2 mm is not clinically useful.

Plot had 89% (70/79) agreement in a clinically significant range (2 mm). MRI measurement modality had moderate to good results for measuring the interspinous space when compared to intraoperative anthropometric measurements, and excellent results between observer measurements. There is no other direct study of the anthropometric space specified in the lumbar interspinous spacer procedure, so a comparison of these averages cannot be made. However, the study of the interspinous space by Jang and Park showed MRI measurements within the reference range of ISS sizes for the lumbar spinal region. Measurements ranged from 8 to 16 mm between contiguous vertebrae, corresponding with our interspinous measurements' range.¹⁴

MRI is the most common imaging modality used to diagnose LSS and, with specified classification systems, has shown a good correlation to clinical manifestations.²² While studies have used MRI to evaluate measurements of the lumbar intervertebral

disc and interspinous anthropometric parameters,¹⁴ none have been performed to determine if MRI can evaluate intraoperative measurements for minimally invasive lumbar spinal procedures, as performed here. Additionally, prior studies have validated MRI as a predictive measuring tool by comparing it with reference standard arthroscopic measurements of labral width.^{15–17} The present study amounts to a feasibility study. Therefore, the study is not designed to replace current clinical best practices but instead establishes moderate to good reliability between intraoperative and MRI measurements, suggesting MRI is a valid tool to measure the intraoperative space for the ISS procedure. The studies mentioned above using MRI as an intraoperative predictive measurement modality showed greater reliability; however, this can likely be attributed to variation in methods, discussed in our limitations. Due to our study's clinical agreement with current ISS sizes used for the ISS procedure, MRI is

functional in evaluating the interspinous space. A smaller average measurement on MRI than intraoperatively is clinically acceptable within the 2 mm margin, as the five available ISS sizes vary by 2 mm. Repeat and further study must be performed to determine whether MRI can accurately predict the interspinous space and potentially obviate intraoperative measurements.

Although intraoperative measurement is the current best practice model for the ISS procedure, there are no guidelines or tools to validate this measurement comparatively. Correct placement is essential to improve symptoms and avoid slipping of the device from the ISS if the implanted device is too small or fracturing if the device is too large.¹¹ There was a 6.4% complication rate in our study for the ISS procedure, which is lower as compared to the aforementioned multicenter study complication rate of 7.8%.¹¹ These complications often result in secondary surgical evaluation.¹⁸ Revision data was not collected as part of this study but another study found reasons for revision to include: acute worsening of low-back pain or lack of improvement (45 cases) recurrence of symptoms after an initial good outcome (42 cases), and implant dislocation (20 cases).¹¹ Determining the interspinous space preoperatively would aid surgical planning and intraoperative decision-making by locating the correct anatomical positioning before operating under fluoroscopy. Thus, theoretically, decreasing incorrect implant sizing, as well as time under fluoroscopy and overall time under anesthesia. MRI measurements are especially clinically significant in cases of complex anatomy or poor intraoperative fluoroscopic view. A comparable value of individual interspinous space could help surgeons ensure appropriate location and increase intraoperative confidence in device placement.

Limitations

This study had several limitations that must be noted. The MRI measurements were performed by someone other than board-certified radiologists due to time and resource limitations at our institution for this study. Compared with other studies using MRI as a predictive model for intraoperative measurements, radiologist observers were the main difference in methods, which likely contributed to the greater reliability observed in those studies due to increased expertise in imaging modalities.^{15–17} Due to the study's retrospective nature and the impracticality of having multiple chronic pain fellows in a single ISS procedure, only one intraoperative measurement could be taken for a single case. Intraoperative measurement is the reference standard for predicting the space where the ISS will be inserted. This study showed this measurement modality to correlate strongly with the ISS size used (0.807, $p < 0.001$). A third limitation of the study was the technique used in taking intraoperative measurements on MRI. Boney

anatomical landmarks were used to take measurements on the PACS workstation. The anatomical distribution of tissue types in the interspinous space includes soft tissue and bone, where soft tissue surrounds bone.

Further adjustment to compensate for soft tissue in the interspinous space may account for the difference between MRI and intraoperative measurement. Using CT in addition to MRI measurement would aid in accounting for minor discrepancies between bone and soft tissue. As the study was performed retrospectively with blinding to ISS sizes and intraoperative measurements, no bias or confounding variables were of note. Additionally, further studies using radiologist observers should evaluate MRI measurement ability in a predictive capacity for the intraoperative space through a prospective randomized controlled trial. A more acute clinical goal for this research is adopting a standard MRI measurement protocol at the lumbar level of ISS placement for comparative use intraoperatively.

CONCLUSION

Good agreement and moderate reliability were found between MRI and intraoperative measurements of the interspinous space for the ISS procedure in treating LSS. There was not a significant difference in the average between the two measurement modalities, and differences were in a clinically acceptable window. There was excellent reliability between observer measurements. In conclusion, MRI was shown to be an acceptable modality for measuring the interspinous space for ISS procedure. Preoperatively measuring the interspinous space with MRI can aid in surgical decision-making while taking intraoperative measurements, serving as a reference and streamlining workflow. The adoption of a standard preoperative MRI measurement protocol may decrease patient time under fluoroscopy and would validate device placement location for surgeons, likely resulting in decreased complications of incorrect sizing, causing device slipping or fracture, commonly leading to revision surgery. Further study is necessary to determine if MRI measurements can serve as a predictive model of the intraoperative space in the ISS procedure, and potentially replace the necessity of intraoperative measurement.

AUTHOR CONTRIBUTIONS

Charles Nelson: Acquisition and data, analysis and interpretation of data, drafting of the manuscript, critical revision of the manuscript for important intellectual content. **Chuanhong Liao:** Analysis and interpretation of data, drafting of the manuscript, statistical analysis. **Tariq Malik:** Conception and design, acquisition and data, analysis and interpretation of data, drafting of the manuscript, critical revision of the manuscript for important intellectual content, administrative, technical or material support and supervision.

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The authors have no sources of funding to declare for this manuscript.

CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest.

DATA AVAILABILITY STATEMENTS

The data that support the findings in this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

CONSENT

Waiver of consent process and consent documentation – IRB Approval (IRB23-0705–University of Chicago Biological Sciences Division/University of Chicago Medical Center). The research did not report any identifiable private information. Private information was viewed by research personnel for the purposes of extracting study data. Since certain information could only be extracted by examining the individual report (i.e. individual elements of the test results were not individual reported in the medical record), the study could not be carried out without directly accessing patient charts. Many, if not most, potential subjects were no longer seen at UChicago and presumably none of the potential subjects are currently followed by pain medicine. It was not feasible to approach subjects for consent to participate in the study because they were no longer reachable by the study team.

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